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09/125,908 11/03/98 BLASCHUK 0 1000086.49 ^{KM}

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EXAMINER

DECLoux, A

ART UNIT

PAPER NUMBER

1644

DATE MAILED:

03/27/01 ¹⁴

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/185,908

Applicant(s)

Blaschuck et al

Examiner

DeCloux, Amy

Group Art Unit

1644



☒ Responsive to communication(s) filed on mailed 12-19-00

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) 2-63 is/are pending in the application

Of the above, claim(s) 9, 10, 14-26, 44, 45, 50, 51, 56, 57, 62, and 63 is/are withdrawn from consideration

☐ Claim(s) is/are allowed.

☒ Claim(s) 2-8, 11-13, 27-43, 46-49, 52-55, and 58-61 is/are rejected.

☐ Claim(s) is/are objected to.

☐ Claims are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number)

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received:

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s).

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

DETAILED ACTION

1. Applicant's amendment, mailed 12-29-00 (Paper No. 12), is acknowledged.
2. Applicant's election of Group I, claims 1-20, 27-43, 46-49, 52-55 and 58-61 in Paper No. 10, mailed April 10, 2000, and the species WKIYSYAG (SEQ ID NO:34) as the specific species to which the claims may be restricted if no generic claim is held allowable.
3. Claims 9-10, and 14-20 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species, there being no allowable generic or linking claim.
4. The rejections of record can be found in the previous Office Action mailed 6/30/00 (Paper No. 11). In view of applicant's amendment, mailed 12-29-00 (Paper No. 12), all the 112 2nd rejections, except against claim 5 and the 102(b) rejection anticipated by Ruoslahti et al have been withdrawn; however, the 112 first enablement and written description rejections, the 102(b) rejection anticipated by Bult, and the 112 2nd rejection of claim 5 only, have been maintained. Additionally, a new grounds of rejection has been applied to newly amended claims 2-3, 5-8, 11-13, 21-23, 27-43, 46-49, 52-55 and 58-61.
5. Regarding the art rejections:

In the previous Office Action mailed 6/30/00 (Paper No. 11), the elected species WKIYSYAG (SEQ ID NO:34) was found free of the prior art, so the search was extended to IYSY (SEQ ID NO:2) which, like SEQ ID NO:34, is also recited in claim 40. As stated in a 102(b) art rejection in said previous office action, SEQ ID NO:2 was anticipated by Bult et al and therefore the search was ended. The 102(b) rejection anticipated by Bult has been maintained in this present action.

Also the cyclic peptide CICSYC (SEQ ID NO:59) was inadvertently searched in said previous office action, and was found to be anticipated in a 102(b) art rejection by Ruoslahti et al. In view of applicant's amendment, mailed 12-29-00 (Paper No. 12), the 102(b) rejection anticipated by Ruoslahti et al has been withdrawn. However the search has not been extended to other cyclic peptides since art was found on the specific species WKIYSYAG (SEQ ID NO:34) to which the claims may be restricted if no generic claim is held allowable. SEQ ID NO 2

With respect to the 102(b) rejection anticipated by Bult, applicants traverse the rejection on the grounds that said reference describes the entire genome sequence of

Methanococcus jannaschii and depicts many open reading frames, and that there is no indication that the sequence is correct or that it is a functional open reading frame. However, the examiner has attached a genbank submission of the cDNA of the mRNA of the gene encoding a protein comprising the sequence IYSY by Kohara (1995) that indicates that said genomic sequence is correct and functions in an open reading frame. Therefore, though applicant's arguments have been carefully considered the rejection is maintained and repeated below for applicant's convenience.

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 2, 35 and 40 are rejected under 35 U.S.C. 102(b) as anticipated by Bult et al. (Science 273:1058-1073, 1996).

Bult et al teach a 47mer protein that comprises the sequence IYSYX (see entire article) comprising at least 5 consecutive amino acids of SEQ ID NO:1. Therefore, the referenced teachings anticipate the claimed invention.

8. Regarding the **112 first rejections**: though applicant's arguments have been carefully considered all the 112 first paragraph rejections are maintained.

9. Regarding the enablement rejection described in section 3 of the previous office action, applicant traverses the rejection on the grounds that their invention is enabled and that claudin CAR sequences comprising the consensus sequence of SEQ ID NO:1 can be used to mediate cell adhesion by claudin molecules. The examiner agrees that applicants have disclosed that an agent comprising said claudin CAR sequence is capable of modulating claudin-mediated processes, such as cell adhesion, (see page 14, lines 10-21 of the instant specification), and also agrees with applicant that an assertion within a specification is presumed to be correct. However, the more unpredictable an area is, the more enablement is required. That this area is unpredictable is evidenced by generation by applicant of this deduced consensus amino acid sequence for a claudin CAR sequence (SEQ ID NO:1), based on a sequence homology alignment of the amino acid sequences of extracellular domain one of representative mammalian claudins as indicated in Figure 1 of the instant specification. In view of the fact that there is no clear guidance from Applicant's specification that an agent comprising SEQ ID NO:1 is capable of modulating claudin-

mediated processes, such as cell adhesion, especially when applicant has not disclosed the sequence identity of CAR containing peptides that actually reduce cell adhesion in the disclosed example, nor the 9 amino acid CAR sequence used to make the antibodies that have cell adhesion modulating activity as disclosed in Examples 2 and 4. The only proposed uses for the an agent comprising the claimed CAR sequence are based upon an alignment with other mammalian claudins, and there is no predictability that this small sequence identity (or which part(s) thereof) would confer the biological activities including modulating claudin-mediated processes, such as cell adhesion, to an agent comprising the claimed CAR sequence (SEQ ID NO:1) because Applicant has not disclosed where the biological activity of cell adhesion of the claudin resides within the (SEQ ID NO:1) and if this consensus sequence alone is sufficient. Therefore, though applicant's arguments have been carefully considered, said rejection is maintained.

10. Regarding the written description rejection of claims 2-8, 11-13, 27-43, 46-49, 52-55 and 58-61, described in section 4 of the previous office action, applicant traverses the rejection on the grounds that one of ordinary skill in the art would know that independently selected amino acids in the claudin CAR consensus sequence (SEQ ID NO:1) may be any amino acids the consensus sequence. However, even if the consensus sequence is adequately described, applicant has not addressed the inadequate description of a claudin CAR sequence, specifically what sets apart claudin sequences as a genus from sequences which are not claudin sequences, as noted in the last few sentences of this written description rejection described in section 4 of the previous office action. Therefore, though applicant's arguments have been carefully considered, said rejection is maintained.

11. Regarding the enablement rejection of claims 33-34 and 38-39, described in section 5 of the previous office action, applicant traverses the rejection on the grounds that the instant specification is commensurate with the scope of the claims, and that it teaches a variety of sequences that may be combined with claudin CAR sequences. However, since the recited cell adhesion modulating agent comprising a claudin CAR sequences is not adequately described, it is not clear which cell adhesion recognition sequences are of the genus of claudin CAR sequences, and therefore the scope is indefinitely large. Therefore, though applicant's arguments have been carefully considered, said rejection is maintained.

Regarding the 112 second rejections;

12. Only the 112 second rejection against claim 5 has been maintained. It appears that applicant inadvertently did not alter claim 5 as indicated by applicant on page 10 in the "Remarks" section of applicant's amendment, and therefore it is repeated below for applicant's convenience.

13. The following is a quotation of the second paragraph of 35 U.S.C. 112:
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the Applicant regards as his invention.

14. Claim 5 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

A) Claims 5 is indefinite in the recitation of an agent is a peptide ranging in size from 3 to 50 amino acid residues since claims 2, 3 and 4 encompass 5, 7 and 8 consecutive amino acid residues of SEQ ID NO:1, respectively.

15. With regards to the **provisional double patenting rejection**: applicants submit that this rejection can be more appropriately addressed when the present claims are otherwise in condition for allowance. In view of applicant's amendment, however, the double patenting rejection has been withdrawn. However, the examiner notes that the applicant's amendment, while obviating the double patenting rejection, have at the same time raised a new matter issue (see below).

New Grounds of Rejection:

16. The following is a quotation of the first paragraph of 35 U.S.C. 112:
The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Newly amended claims 2-3, 5-8, 11-13, 27-43, 46-49, 52-55 and 58-61 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The instant claims are not supported by the specification or by the claims as originally filed. There is no support in the specification or claims as originally filed for the recitation "wherein Aaa is not glycine when Lys/Arg is Arginine and Baa is aspartic acid". There is no written description of the claimed invention in the specification or claims as originally filed. Thus the claimed invention constitutes **new matter**, by virtue of introducing a negative limitation, see Ex parte Grasselli 231 USPQ 393.

17. No claim is allowed.

18 Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy DeCloux whose telephone number is (703) 306-5821. The examiner can normally be reached Monday through Friday from 9:00 am to 6:00 pm. a message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Amy DeCloux, Ph.D.
Patent Examiner
Group 1640, Technology Center 1600
March 26, 2001

David A. Saunders

DAVID SAUNDERS
PRIMARY EXAMINER
ART UNIT 182

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